LIFEPAK 12 defibrillator/monitor series

Performance Inspection Procedure Checklist

Medtronic PHYSIO-CONTROL

Model # _____

Serial # _____ **Department/Location** _____

Type of PIP: **Post-Repair** ❒ **Annual** ❒ **Performed By** _____

Date _____

Inspection		Pass	Fail	Comments
A	**Physical Inspection**	❒	❒	
B	**User Selected Manual Mode**	Manual Mode:_____		

Testing		Pass	Fail	Comments
1	**Power On**			
	a. Record software version that appears during Self Test.	Version: 3011371- _____		
	b. Confirm the Service indicator is off.	❒	❒	
	c. Confirm the device completes the Power On sequence.	❒	❒	
2	**Record Operating Data**			

Total Shocks _____

360 J Shocks ☐ _____

275-325 J Shocks ☐ _____

0-200 J Shocks ☐ _____

Power Cycle Count _____
Pacing Count (if installed) _____
Shock Count _____
Power On Time _____
Printer On Time _____
SpO2 Operating Time (if installed) _____
Defib Storage Cap Value _____

3	**Keypads**			
	Confirm all control text boxes are highlighted.	❒	❒	
4	**Printer**			
	Confirm printed test strip and CHECK PRINTER message.	❒	❒	
5	**Audio**			
	Confirm voice messages and tones are clear and not distorted.	❒	❒	
6	**Power Source Management**			
	a. Confirm battery switching.	❒	❒	
	b. Confirm auxiliary power switching.	❒	❒	
	c. Confirm defibrillator charge current with auxiliary power.	❒	❒	
7	**12-Lead ECG Characteristics** [Alternative: 3-Lead ECG Characteristics]			
	a. Confirm leads off screen messages.	❒	❒	
	b. Record 12-Lead ECG gain (tolerance 36 to 44 mm).	Amplitude: _____ mm		
8	**3-Lead ECG Characteristics** [Alternative: 12-Lead ECG Characteristics]			
	a. Confirm leads off screen messages.	❒	❒	
	b. Record 3-Lead ECG gain (tolerance 36 to 44 mm).	Amplitude: _____ mm		
9	**QUIK-COMBO Impedance Sense**			
	a. Confirm display of PADDLES LEADS OFF message. [370 ohms]	❒	❒	
	b. Confirm no display of PADDLES LEADS OFF message. [238 ohms]	❒	❒	

Testing		Pass	Fail	Comments
10	**QUIK-COMBO User Test** [Alternative: Standard Paddles User Test]			
	Confirm UUT passes QUIK-COMBO User Test	❒	❒	
11	**QUIK-COMBO Delivered Energy**			
	2 J – Record delivered energy (tolerance 1.0 to 3.0 J).	Energy Level: _____ J		
	10 J – Record delivered energy (tolerance 9.0 to 11.0 J).	Energy Level: _____ J		
	70 J – Record delivered energy (tolerance 65.1 to 74.9 J).	Energy Level: _____ J		
	200 J– Record delivered energy (tolerance 186.0 to 214.0 J).	Energy Level: _____ J		
	360 J– Record delivered energy (tolerance 334.8 to 385.2 J).	Energy Level: _____ J		
12	**QUIK-COMBO ECG Characteristics** [Alternative: Standard Paddles ECG Characteristics]			
	a. Record QUIK-COMBO ECG gain (tolerance 36 to 44 mm; 38 to 50 mm with QED-6).	Amplitude: _____ mm		
	b. Record Fast-Restore duration (maximum 12.5 mm).	Duration: _____ mm		
13	**QUIK-COMBO Synchronous Cardioversion** [Alternative: Standard Paddles Synchronous Cardioversion]			
	Record Sync delay (maximum 60 ms):	Sync: _____ ms		
14	**Standard Paddles User Test** [Alternative: QUIK-COMBO User Test]			
	Confirm UUT passes Standard Paddles User Test	❒	❒	
15	**Standard Paddles Delivered Energy** [Alternative: QUIK-COMBO Delivered Energy]			
	2 J – Record delivered energy (tolerance 1.0 to 3.0 J).	Energy Level: _____ J		
	10 J – Record delivered energy (tolerance 9.0 to 11.0 J).	Energy Level: _____ J		
	70 J – Record delivered energy (tolerance 65.1 to 74.9 J).	Energy Level: _____ J		
	200 J– Record delivered energy (tolerance 186.0 to 214.0 J).	Energy Level: _____ J		
	360 J– Record delivered energy (tolerance 334.8 to 385.2 J).	Energy Level: _____ J		
16	**Standard Paddles Defibrillation Isolation**			
	Record isolation delivered energy (maximum 18 J).	Energy Level: _____ J		
17	**Standard Paddles ECG Characteristics** [Alternative: QUIK-COMBO ECG Characteristics]			
	a. Record Standard Paddles ECG gain (tolerance 36 to 44 mm; 38 to 50 mm with QED-6).	Amplitude: _____ mm		
	b. Record Fast-Restore duration (maximum 12.5 mm).	Duration: _____ mm		
18	**Standard Paddles Synchronous Cardioversion** [Alternative: QUIK-COMBO Synchronous Cardioversion]			
	Record Sync delay (maximum 60 ms).	Sync: _____ ms		
19	**Pacer Option Characteristics** [Alternative: No Pacer Option Characteristic]			
	a. Confirm leads off detection.	❒	❒	
	b. 10 ma – Record current (tolerance 5 to 15 ma).	Current Level: _____ ma		
	50 ma – Record current (tolerance 45 to 55 ma).	Current Level: _____ ma		
	100 ma– Record current (tolerance 95 to 105 ma).	Current Level: _____ ma		
	150 ma– Record current (tolerance 142.5 to 157.5 ma).	Current Level: _____ ma		
	200 ma– Record current (tolerance 190 to 210 ma).	Current Level: _____ ma		
	c. Record pulse width (tolerance 19.0 to 21.0 ms).	Pulse Width: _____ ms		
20	**No Pacer Option Characteristic** [Alternative: Pacer Option Characteristics]			
	Confirm successful pacing calibration routine.	❒	❒	
21	**ECG Analog Output**			
	Record signal amplitude (tolerance 0.85 to 1.15 Vp-p).	Amplitude: _____ Vp-p		
22	**Oximeter** [if SpO2 option is installed]			
	Confirm SpO2 reading is between 90% and 100%.	❒	❒	

Testing	Pass	Fail	Comments
23 **Capnometer** [if EtCO2 option is installed]			
a. Confirm change in vacuum reading is less than 20 mBars.	❒	❒	
b. Confirm CO2 concentration reading is 5% ±0.5%.	❒	❒	
24 **Blood Pressure Meter** [if NIBP option is installed]			
a. Confirm 50 mmHg, 100 mmHg, 150 mmHg, and 200 mmHg readings agree within ±3 mmHg.	❒	❒	
b. Confirm the overpressure switch activates at 285 mmHg ±10 mmHg.	❒	❒	
c. Confirm LEAKAGE TEST OK message.	❒	❒	
25 **PC Card** [omit if user does not use a PC Card]			
Confirm PC Card DIALING message.	❒	❒	
26 **Chassis Leakage Current**			
a. Neutral Closed, Polarity Normal, Lead-Chassis, Normal.	❒	❒	
b. Neutral Closed, Polarity Normal, Lead-Chassis, Fault.	❒	❒	
c. Neutral Closed, Polarity Reversed, Lead-Chassis, Normal.	❒	❒	
d. Neutral Closed, Polarity Reversed, Lead-Chassis, Fault.	❒	❒	
27 **Earth Leakage Current**			
a. Neutral Closed, Polarity Normal, Earth.	❒	❒	
b. Neutral Open, Polarity Normal, Earth.	❒	❒	
28 **Paddles Source Leakage Current** [Alternative: QUIK-COMBO Source Leakage Current]			
a. Neutral Closed, Polarity Normal, Lead-Gnd, Normal.	❒	❒	
b. Neutral Closed, Polarity Normal, Lead-Gnd, Fault.	❒	❒	
c. Neutral Closed, Polarity Normal, Lead-Lead, Normal.	❒	❒	
d. Neutral Closed, Polarity Normal, Lead-Lead, Fault.	❒	❒	
29 **Paddles Sink Leakage Current** [Alternative: QUIK-COMBO Sink Leakage Current]			
Neutral Closed, Polarity Normal, Lead Iso.	❒	❒	
30 **QUIK-COMBO Source Leakage Current** [Alternative: Paddles Source Leakage Current]			
a. Neutral Closed, Polarity Normal, Lead-Gnd, Normal.	❒	❒	
b. Neutral Closed, Polarity Normal, Lead-Gnd, Fault.	❒	❒	
c. Neutral Closed, Polarity Normal, Lead-Lead, Normal.	❒	❒	
d. Neutral Closed, Polarity Normal, Lead-Lead, Fault.	❒	❒	
31 **QUIK-COMBO Sink Leakage Current** [Alternative: Paddles Sink Leakage Current]			
Neutral Closed, Polarity Normal, Lead Iso.	❒	❒	
32 **ECG 12-Lead Source Leakage Current** [Alternative: ECG 3-Lead Source Leakage Current]			
a. Neutral Closed, Polarity Normal, Lead-Gnd, Normal.	❒	❒	
b. Neutral Closed, Polarity Normal, Lead-Gnd, Fault.	❒	❒	
c. Neutral Closed, Polarity Reversed, Lead-Gnd, Normal.	❒	❒	
d. Neutral Closed, Polarity Reversed, Lead-Gnd, Fault.	❒	❒	
e. Neutral Closed, Polarity Normal, Lead-Lead, Normal.	❒	❒	
f. Neutral Closed, Polarity Normal, Lead-Lead, Fault.	❒	❒	
g. Neutral Closed, Polarity Reversed, Lead-Lead, Normal.	❒	❒	
h. Neutral Closed, Polarity Reversed, Lead-Lead, Fault.	❒	❒	
33 **ECG 12-Lead Sink Leakage Current** [Alternative: ECG 3-Lead Sink Leakage Current]			
Neutral Closed, Polarity Normal, Lead Iso.	❒	❒	

Testing		Pass	Fail	Comments
34	**ECG 3-Lead Source Leakage Current** [Alternative: ECG 12-Lead Source Leakage Current]			
	a. Neutral Closed, Polarity Normal, Lead-Gnd, Normal.	❒	❒	
	b. Neutral Closed, Polarity Normal, Lead-Gnd, Fault.	❒	❒	
	c. Neutral Closed, Polarity Reversed, Lead-Gnd, Normal.	❒	❒	
	d. Neutral Closed, Polarity Reversed, Lead-Gnd, Fault.	❒	❒	
	e. Neutral Closed, Polarity Normal, Lead-Lead, Normal.	❒	❒	
	f. Neutral Closed, Polarity Normal, Lead-Lead, Fault.	❒	❒	
	g. Neutral Closed, Polarity Reversed, Lead-Lead, Normal.	❒	❒	
	h. Neutral Closed, Polarity Reversed, Lead-Lead, Fault.	❒	❒	
35	**ECG 3-Lead Sink Leakage Current** [Alternative: ECG 12-Lead Sink Leakage Current]			
	Neutral Closed, Polarity Normal, Lead Iso.	❒	❒	
36	**SpO2 Source Leakage Current** [If SpO2 option is installed]			
	a. Neutral Closed, Polarity Normal, Lead-Gnd, Normal.	❒	❒	
	b. Neutral Closed, Polarity Normal, Lead-Gnd, Fault.	❒	❒	
	c. Neutral Closed, Polarity Reversed, Lead-Gnd, Normal.	❒	❒	
	d. Neutral Closed, Polarity Reversed, Lead-Gnd, Fault.	❒	❒	
37	**SpO2 Sink Leakage Current** [If SpO2 option is installed]			
	Neutral Closed, Polarity Normal, Lead Iso.	❒	❒	
38	**AC Power Adapter** [omit if user does not use a AC Power Adapter]			
	a. Confirm auxiliary power switching.	❒	❒	
	b. Confirm defibrillator charge current with auxiliary power.	❒	❒	
39	**DC Power Adapter** [omit if user does not use a DC Power Adapter]			
	a. Confirm auxiliary power switching.	❒	❒	
40	**Power Adapter Chassis Leakage Current**			
	a. Neutral Closed, Polarity Normal, Lead-Chassis, Normal.	❒	❒	
	b. Neutral Closed, Polarity Normal, Lead-Chassis, Fault.	❒	❒	
	c. Neutral Closed, Polarity Reversed, Lead-Chassis, Normal.	❒	❒	
	d. Neutral Closed, Polarity Reversed, Lead-Chassis, Fault.	❒	❒	
41	**Power Adapter Earth Leakage Current**			
	a. Neutral Closed, Polarity Normal, Earth.	❒	❒	
	b. Neutral Open, Polarity Normal, Earth.	❒	❒	
42	**Power Adapter QUIK-COMBO Source Leakage Current**			
	a. Neutral Closed, Polarity Normal, Lead-Gnd, Normal.	❒	❒	
	b. Neutral Closed, Polarity Normal, Lead-Gnd, Fault.	❒	❒	
	c. Neutral Closed, Polarity Normal, Lead-Lead, Normal.	❒	❒	
	d. Neutral Closed, Polarity Normal, Lead-Lead, Fault.	❒	❒	